may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . . ." *See* 21 U.S.C. § 352(a) and (f).

149. The term "labeling" encompasses the actual label attached to the drug's immediate container, as well as all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 C.F.R. § 321(m). The term has been construed to include a variety of drug company promotional materials, including booklets, pamphlets, and literature that is textually related to the product, even when disseminated without the presence of the drug. *See Kordel v. United States*, 335 U.S. 345, 349 (1948); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957). In determining if a drug's labeling or advertising is misleading and thus misbranded, one must examine "(among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article" as described by the labeling or advertising or the customary or usual use of the article. 21 U.S.C. § 321(n).

150. In order for a drug's labeling to include "adequate directions for use," the directions must allow a layman to use the drug safely and for its "intended use." *See* 21 C.F.R. § 201.5. The "intended use" of a drug refers to "the objective intent of the person legally responsible for the labeling of drugs." *See* 21 C.F.R. § 201.128. "The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article," and "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id*. Thus, if a manufacturer

promotes a drug for a use for which the label does not provide adequate directions for use or is otherwise false and misleading, misbranding has occurred, regardless of Medicaid or Medicare Part D's reimbursement of the drug for this use.

151. Over the years, the FDA has issued regulatory guidances to aid manufacturers in distinguishing between these illegal marketing strategies and legitimate non-promotional dissemination of information on off-label uses, by setting forth factors to determine whether a manufacturer's dissemination of information is actually promotional. These guidances make it clear that pharmaceutical manufacturers cannot use reprints, reference texts or Continuing Medical Education ("CME") programs as tools to promote off-label uses. *See* Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed.Reg. 52800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed.Reg. 52800 (Oct. 8, 1996); Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed.Reg. 64074 (Dec. 3, 1997); Guidance for the Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 Fed.Reg. 1694-01 (Jan. 13, 2009). None of these guidances has changed the FDA's long-standing prohibition against marketing and promoting of approved drugs for off-label uses.

ii. Reimbursement of Off-Label Prescription Drugs under Medicaid

152. In addition to meeting the FDA drug approval requirements, Organon applied for and received Medicaid coverage for Remeron and Remeron SolTab in each of the fifty states, including the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island,

Tennessee, and Texas, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. As a general rule, to be reimbursable under a state's Medicaid program, a drug must be included on the state's formulary. Each state has its own means of deciding coverage, but federal law sets forth requirements states must meet in excluding or restricting coverage. *See* 42 U.S.C. § 1396r-8. A state may exclude or restrict coverage of a drug in four instances:

(1) the prescribed use is not for a medically accepted indication;
(2) the drug is on a list of drugs excluded by the state from Medicaid coverage;
(3) the drug manufacturer agreed to the restrictions on the drug in its rebate agreement with Medicaid; or
(4) the drug was excluded from the state's drug formulary.

31 U.S.C. § 1396r-8(d)(1). In addition, states may use prior authorization programs or preferred drug lists to control potential abuses of drugs, such as prescriptions for an indication that is not a medically accepted indication.

153. A "medically accepted indication" is a use that is listed in the labeling approved by the FDA or "the use of which is supported by one or more citations included or approved for inclusion in" one of the drug compendia identified by the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6). These compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(b)(i). The United States Government and the states interpret "supported by" to require "some form of corroboration or validation." S*ee* Centers for Medicare and Medicaid Release No. 141 (May 4, 2006) ("The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II).").

154. States may establish drug formularies if they meet the following requirements. *See* 42 U.S.C. § 1396r-8(d)(4). The formulary must be developed by a committee consisting of pharmacists, physicians and other qualified individuals appointed by the governor or by the state's Drug Use Review ("DUR") board consisting of healthcare professionals who have recognized knowledge and expertise in the prescription, dispensing and monitoring of outpatient drugs, drug use review, and medical quality assurance. 42 U.S.C. § 1396r-8(d)(4)(A) and § 1396r-8(g)(3).

155. The formulary must include every drug for which a manufacturer has entered into a Medicaid rebate agreement. 42 U.S.C. § 1396r-8(d)(4)(B). The state may, however, exclude a drug from the formulary if: (1) the drug is used for an on-label use -- or an off-label use that is a medically accepted indication based on compendia -- but the drug does not have a significant, clinically meaningful therapeutic advantage over other drugs on the formulary; and (2) the state provides a written explanation, which is available to the public, of why the drug is excluded. 42 U.S.C. § 1396r-8(d)(4)(C). Finally, any drugs excluded from the formulary must nevertheless be available to Medicaid enrollees under a prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D).

156. States generally have some method for drug manufacturers to request that its drug be added to the states' "preferred drug lists." In the majority of states, the Pharmaceutical and Therapeutics committee or the DUR board makes the decision on whether to add drugs to the state Medicaid program's preferred drug list. Generally, these committees announce that they will conduct a review of a class of drugs. At that time, a drug manufacturer may submit information to the committees to be considered for the drug list. A minority of states, such as Indiana, Montana, Nevada and Texas, require drug manufacturers to submit an application to be

placed on the drug list. As part of the Texas application, drug manufacturers are required to expressly certify compliance with all laws, regulations and rules applicable to the Medicaid program, including the federal and state Anti-Kickback statutes.

157. Pharmaceutical Therapeutics Committees and DUR boards are required to continually "assess data on drug use against predetermined standards," using the compendia as the source for these standards. 42 U.S.C. § 1396r-8(g)() and (2). These standards include but are not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, drug-drug interactions. *Id*. The States' continual assessment of drug data permits them the flexibility to determine the appropriate scope, duration, and limitations on coverage of drugs on their formularies.

B. Organon's Off-Label Marketing Scheme

158. As described below, Organon engaged in a nationwide off-label marketing scheme that not only violated the FDA prohibitions against marketing off-label uses of drugs and illegally misbranding drugs, but also violated the Anti-Kickback statute. Further, upon information and belief, Organon purposefully manipulated drug compendia, such as DRUGDEX, and caused them in some cases to list desired off-label uses. For example, the 2008 edition of DRUGDEX lists two studies on the use of mirtazapine (Remeron and Remeron SolTab) in treating depressed patients for anxiety. The studies state that the drug and financial support for the study were provided by Organon. In addition to uses listed in the drug compendia, Organon also promoted other off-label uses that do not appear in any of the drug compendia, such as insomnia, weight gain and anxiety. As a result of this nationwide scheme, Organon reaped profits beyond those it would have achieved from legitimate promotion.

i. FDA Approval of Remeron and Remeron SolTab

159. The FDA approved Remeron tablets on June 14, 1996 and Remeron SolTab on January 12, 2001. Both drugs are indicated for the treatment of depression, specifically for major depressive episodes. Neither drug has been approved for use in children and adolescents. The Diagnostic and Statistical Manual for Mental Disorders 4th edition ("DSM-IV") defines a major depressive episode as a prominent and relatively persistent depressed mood that interferes with daily functioning along at least five of the following nine symptoms: 1) depressed mood, 2) loss of intent in usual activities, 3) significant change in weight and/or appetite, 4) insomnia (inability to sleep) or hypersomnia (excessive daytime sleepiness), 5) psychomotor agitation or retardation, 6) increased fatigue, 7) feelings of guilt or worthlessness, 8) slowed thinking or impaired concentration, and/or 9) suicidal ideation or attempt.

160. The FDA-approved labeling for both drugs includes warnings and precautions. In particular, the labeling warns that use of Remeron and Remeron SolTab may result in somnolence (drowsiness), increased appetite or weight gain, and even anxiety. But instead of warning customers of the side effects of Remeron and Remeron SolTab, Organon initiated an off-label scheme aimed at marketing these side effects to customers. Furthermore, Organon made the off-label claim that Remeron and Remeron SolTab were effective treatments for patients with anxiety, despite a 1999 warning from the FDA that this claim was false and misleading.

161. The FDA-approved labeling for Remeron SolTab also noted that caution should be used in treating geriatric[3] patients with Remeron SolTab. Remeron SolTab is metabolized mainly by the kidney; thus, patients with impaired renal function are less likely to rid their bodies of the drug. The label warns that "Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection." The labeling also advised that

[3] The FDA defines "geriatric" as including patients 65 years of age and older. 21 C.F.R. § 201.57(f)(10).

sedating drugs, like Remeron SolTab, may "cause confusion and over-sedation in the elderly." Despite these concerns, Organon created a plan to market Remeron and Remeron SolTab as the "ideal" antidepressant for elderly patients.

ii. Off-Label Marketing of Remeron and Remeron SolTab

162. Remeron never achieved "household name" status like Prozac, Paxil or Zoloft, as Organon had hoped. This was due in part to Remeron's two most common side effects, somnolence and weight gain, which were troublesome to most depression sufferers. Realizing that those side effects could be framed as "positive" for one patient profile—the elderly patient, Organon devised a scheme to market these attributes to healthcare providers, as though the side effects were approved indications. Organon positioned Remeron as the "ideal therapy for older depressed patients who experience anxiety and sleep disturbances." Organon refined this message for the long-term care sector and actually trumpeted Remeron's weight gain effect.

163. In addition to promoting Remeron as an anti-anxiety substitute and "playing up" Remeron's side effects of sedation and weight gain, Organon made the off-label claims that Remeron was a good choice among anti-depressants because of Remeron's minimal inhibition of the P450 enzyme and fast onset of action in relieving depression symptoms, such as sleep disturbances.

164. Organon also promoted the off-label use of Remeron in children and adolescents for the treatment of depression, attention deficit disorder ("ADD") and attention deficit hyperactivity disorder ("ADHD").

a. 1999 FDA Warning Letter

165. On January 5, 1999, Organon received a warning letter from DDMAC regarding various promotional materials for Remeron Tablet. *See* Letter from DDMAC to Organon (Jan.

5, 1999), *available at* http://www.fda.gov/CDER/warn/jan99/6950.pdf (last visited Sept. 10, 2008) (hereinafter "Warning Letter"). The Warning Letter advised that some of Organon's representations about Remeron were false and misleading, including but not limited to: 1) Remeron was effective in treating anxiety; 2) Remeron can relieve anxiety induced by selective serotonin reuptake inhibitors ("SSRIs"); 3) the implication that Remeron relieves anxiety symptoms as early as one week of use; 4) Remeron is safer or more effective than SSRIs; 5) Remeron has no significant inhibition of cytochrome P450 enzymes. The DDMAC recommended that Organon immediately cease distribution of materials bearing these messages.

(I) Anti-anxiety

166. The majority of the Warning Letter focused on Organon's representations regarding Remeron's ability to improve anxiety. The Warning Letter stated that the representation that Remeron was effective in treating anxiety was false and misleading because:

> Remeron may relieve depression-associated anxiety to the extent the anxiety is a symptom that is sometimes associated with depression. However, a claim that Remeron is effective in relieving anxiety and materials that focus on Remeron's ability to relieve anxiety are not substantiated.

See Warning Letter. As further evidence that Organon's anti-anxiety representation was false and misleading, the DDMAC pointed out that the FDA-approved product labeling for Remeron listed anxiety as a frequent adverse event, meaning that in some cases Remeron actually causes anxiety. The DDMAC also disapproved of Organon's representation that Remeron can relieve anxiety induced by SSRIs as lacking substantiation. The DDMAC further criticized Organon's claim that Remeron could improve symptoms of anxiety as early as the first week of use as false and misleading because it implied that Remeron worked within the first week to relieve depression, an unsubstantiated claim.

(II) Remeron Is More Effective than SSRIs

167. The DDMAC also condemned Organon's claims that Remeron was more effective than SSRIs as false and misleading. The DDMAC noted this representation implied superiority without substantiation from well-controlled comparative studies

(III) Remeron Lacks Significant Inhibition of Cytochrome P450 Enzymes

168. Finally, the DDMAC criticized Organon's claims that Remeron lacked significant inhibition of Cytochrome P450 enzymes. Cytochrome P450 enzymes are some of the major enzymes involved in the human body's metabolism of drugs. Some drugs inhibit Cytochrome P450 enzymes, causing the drug to accumulate in the bloodstream, potentially leading to heart arrhythmia, cardiac arrest, and even death.

169. Recognizing the importance of the Cytochrome P450 enzymes to physicians and pharmacists, Organon claimed that Remeron Tablet did not inhibit Cytochrome P450 enzymes. In the Warning Letter, the DDMAC found this representation to be false and misleading because no formal drug interaction studies had been conducted to substantiate this claim, and further, Remeron's own FDA-approved labeling stated that it is metabolized by some of the Cytochrome P450 enzymes. Due to these two factors, it was not possible to make a definitive statement about the risks associated with the coadministration of Remeron with other drugs metabolized by the Cytochrome P450 enzymes. The DDMAC thus asked Organon to cease in making this representation.

b. Organon's Continued Misrepresentations About Remeron

170. Even after the DDMAC recommended that Organon cease distribution of materials that stated or implied the violative messages, Organon continued to promote Remeron using these representations. Beginning as early as 2000, Organon positioned Remeron as the

ideal drug for treating older patients with anxiety and sleep disturbances throughout the various customer sectors, including primary care and psychiatrists.

171. In addition, sometime after Remeron SolTab was launched in January 2001, Organon hired pharmacist Dana Saffel to design formal marketing materials, the Toolkit and its accompanying CD, to market these off-label uses of Remeron. The Toolkit was widely used by the Organon Long-Term Care sales force as the primary tool for selling to both long-term care clinicians and long-term care pharmacy consultants. Saffel's cover letter made clear that the Toolkit was designed to be used by long-term care pharmacy providers to persuade pharmacy providers to choose Remeron SolTab as its preferred anti-depressant and to teach these providers how to implement a therapeutic interchange program. Not only did the Toolkit contain Organon's false and misleading representations about Remeron's ability treat anxiety and its lack of inhibition of Cytochrome P450 enzymes, but the Toolkit contained Organon's new plan to market Remeron as a substitute for sedatives and appetite stimulants based on its side effect profile.

172. Section I of the Toolkit was devoted to Remeron's "therapeutic efficacy" and promoted Remeron's sedative, anti-anxiety and weight gain qualities to long-term care administrators. Section I, for example, repeated Organon's violative off-label message that Remeron was effective in treating anxiety. On page 2 of Section I, the Toolkit proclaimed that "[t]he side effect profile of mirtazapine [Remeron] can be quite attractive, especially in the elderly depressed patient with anxiety, agitation, insomnia, and weight loss." *See* Toolkit, Ex. 1. Pages 47 and 48 in Section I of the Toolkit were devoted to using clinical studies to represent that Remeron was effective in reducing anxiety in patients within the first week of treatment. *See* Toolkit, Ex. 1. Moreover, several pages in Section I discussed that Remeron could act as a

substitute for anti-anxiety agents, reducing the need for adjunctive medications. *See* Toolkit, Ex. 1. Section I of the Toolkit also repeated Organon's violative message that Remeron had minimal inhibition of the Cytochrome P450 enzymes. *See* Toolkit, Ex. 1, pp. 9, 82. The Toolkit stated: "Lack of clinically significant P450 inhibition and the relatively low protein binding make clinically significant interactions unlikely." *See id*. at p. 82.

173. In addition, in Section I of the Toolkit, Organon introduced its claim that Remeron could be used as a substitute for sedatives and hypnotics. Throughout the Toolkit, Remeron was praised as improving sleep disturbance. For this reason, Organon claimed, use of Remeron might eliminate the need for the use of a sedative or hypnotic drug as well. For example, on page 43 of Section I, the Toolkit stated: "Mirtazapine [Remeron] can treat insomnia without the use of 'inappropriate' sedative-hypnotics." The Toolkit then urged on page 53 of the same section that "Since up to 90% of patients with depression experience insomnia, using a drug that promotes sleep while also effectively treating depression can be a good therapeutic option." Later in Section I of the Toolkit, Remeron's side effect of somnolence was touted as the most frequently occurring adverse event for Remeron, implying that Remeron may be a substitute for sedatives. *See* Toolkit, Ex. 1, p. 57.

174. The Toolkit also discussed Organon's claim that Remeron could be used as a substitute for appetite stimulants. Pages 44 and 45 of Section I focused on two studies that demonstrated that patients using mirtazapine experienced the adverse effect of weight gain. On page 46, the Toolkit stated: "Since 30 to 50% of NH residents have substandard body weight, using a drug that promotes appetite and weight gain while also effectively treating depression can be a good therapeutic option." Several pages later, the Toolkit exaggerated Remeron's side

effect of weight gain, pointing out that 17% of patients gained weight while using mirtazapine, implying Remeron's usefulness as an appetite stimulant substitute. *See* Toolkit, Ex. 1, p. 57.

175. As discussed above, Section II of the Toolkit, entitled "Contract Evaluation," discussed pharmacy providers' opportunity to increase profits by encouraging the prescribing of Remeron. As part of this discussion, the Toolkit emphasized that in addition to taking advantage of the opportunity to profit, pharmacy providers could increase profits by prescribing Remeron and eliminating the use of adjunctive drug prescriptions for sedatives, anti-anxiety agents, and appetite stimulants. The Toolkit suggested that a provider could save between $21to $215 per month per medication by switching to Remeron and discontinuing these drugs.

176. Finally, Section III of the Toolkit provided step-by-step directions for implementing a therapeutic interchange for Remeron. Section III included notification letters to physicians, facility administrators, directors of nursing and facility for pharmacy providers to use in explaining the reason the pharmacy provider chose Remeron as a preferred drug. In addition, Section III of the Toolkit contained sample recommendations that consultant pharmacists could use to persuade physicians to switch to Remeron SolTab. These notification letters and recommendations not only represented that Remeron SolTab improved anxiety, insomnia and appetite and caused weight gain and therefore could be a substitute for anti-anxiety agents, but that Remeron was more effective than SSRI antidepressants, a claim that, as discussed above, the FDA had already warned Organon was false and misleading. Incredibly, the notification letters also claimed that "SSRI antidepressants such as Zoloft, Prozac, Paxil, and Celexa should not be used when a depressed resident is suffering from insomnia because they can actually *cause* insomnia and anxiety." *See* Toolkit, Ex. 1, Section III (emphasis in original). This, of course,

was the very point the FDA made to Organon as to why Organon's claims that Remeron was effective as an anti-anxiety agent were false and misleading.

c. Organon's Marketing Remeron for Treatment of Depression, ADD and ADHD in Children and Adolescents

177. Although Organon's off-label messages primarily focused on the mature patient, Organon also promoted Remeron for off-label uses in children. For example, an internal Organon marketing plan for the Central Nervous System sector suggests that Remeron's side effects of somnolence and weight gain may be viewed as beneficial in children. A study of physicians' thoughts regarding Organon sales representatives' sales calls prepared by an outside vendor shows that sales representatives discussed off-label uses of Remeron in children. For example, one physician noted that a representative "helped" by providing the physician with statistics and information regarding the use of Remeron for ADD and ADHD in children and adolescents. Another physician stated that the sales representative explained that Remeron helped children, such as those with ADD, calm down and sleep.

178. In sum, Organon engaged in a systematic and widespread marketing scheme to promote several off-label usages of Remeron, at Medicaid's expense. Organon's off-label campaign likely injured patients by leading doctors to prescribe drugs that were medically ineffective and substantially inappropriate. In many cases in which Remeron was prescribed for off-label attributes, it was prescribed in conjunction with another anti-depressant. Remeron's frequent use as "adjunctive therapy" further burdened Medicaid, which was paying for its patients to receive two anti-depressants at the same time. It is not known what physical harm may have been imposed upon elderly patients whose ability to eliminate these and other medications due to decreased renal failure was greatly compromised.

C. Organon's Use of Kickbacks

179. In the long term care sector, the "opportunity to profit" from prescriptions was the prime selling point for Remeron customers, who were mostly LTCPPs rather than physicians. In that sector, Organon used its off-label messages, particularly weight gain, anti-anxiety and somnolence, simply to aid the LTCPPs in justifying to physicians and others facilitating a therapeutic interchange from a competitor antidepressant to Remeron SolTab or from Remeron Tablet to Remeron SolTab.

180. In primary care and other sectors, in contrast, prescribing physicians with no parallel "opportunity to profit" were the targets of Organon's marketing. Within these sectors, Organon used kickbacks to influence physicians in at least two ways. First, in order to disseminate the off-label information described above, Organon needed effective messengers beyond just sales representatives; it needed a small number of high-profile experts in related fields to extol Remeron's virtues to other physicians. Without substantial speaker fees, advisor's fees, grants, and other perks, Remeron simply would not have been able to recruit such "thought and opinion leaders" on the strength of the drug alone.

181. At least as important to increasing Remeron sales were smaller incentives doled out to large numbers of actual prescribers. These took the form of more modest speakers' fees, fees for bogus clinical trials, and gifts in kind, such as lavish weekends at resorts.

182. Whether the kickbacks took the form of bogus speaker programs, honoraria, dinner and lunch meetings, cash payments or other similar schemes, the motive was the same—to lock in patient referrals (i.e. prescriptions). The main targets of Organon's kickback schemes were doctors who had already prescribed a large amount of Organon drugs, were willing to prescribe Organon's drugs for off-label uses, or gave the representatives a listening ear.

i. Speaker Programs

183. Organon's speaker programs were frequently little more than poorly disguised kickback programs. These programs often lacked scientific, medical or educational value because they were largely used as vehicles for promoting off-label messages that were themselves misleading and unfounded.

184. In addition to these junkets, speakers were offered honoraria for their speaking engagements. The amount of speakers' honoraria varied. Organon's payments to these doctors greatly exceeded the fair market value and reasonable compensation ordinarily given to a speaker in a typical arms-length transaction, particularly as the presentations were often short and the audiences small.

ii. Advisory Boards

185. Organon used advisory boards as a way to funnel kickbacks to physicians. Organon would gather physicians for purposes of providing Organon with feedback on how to market its drugs. These advisory boards were open venues where off-label indications of Organon's drugs would be discussed. In exchange for participating in these events, the physicians would receive fees or honoraria.

iii. Preceptorships

186. Another Organon kickback scheme involved preceptorships, arrangements in which a doctor would allow a sales representative to shadow him or her for part of a day (usually four to six hours). The representative then took that opportunity to promote Remeron to the physician. The promotion usually consisted of off-label messages. In exchange for allowing the preceptorship, the doctor would be paid a fee or honoraria for what amounted to a paid marketing campaign.

iv. Gifts in Kind

187. Organon often invited high prescribers to lavish events as a reward for their prescribing activity. Organon's choice of venues and excessive compensation reveal that the focus of these programs was on wining and dining doctors rather than on exchanging scientific and medical information.

v. Fees for Bogus Clinical Trials and Studies

188. Organon paid doctors fees for bogus clinical trials and studies in exchange for prescriptions. For example, Organon offered payment to physicians to participate in the Mature D study. Although Mature D took the form of a research clinical trial, it was, in fact, a marketing ploy designed to induce high-prescribing Remeron tablet general medical practitioners and psychiatrists to become comfortable prescribing Remeron SolTab.

189. These coupled campaigns to market Remeron in an off-label manner and to pay kickbacks to doctors to aid in that campaign and prescribe the drug directly resulted in dramatic increases in its profits for Remeron. In addition to tainting the prescriptions that arose out of such schemes, Organon's kickback and off-label marketing strategies raised the total cost assumed by Medicaid, because doctors, blinded by Organon's remunerations, prescribed Organon drugs that: (a) they would not have prescribed if not for the kickbacks; (b) were medically unnecessary and ineffective; or (c) were more expensive than alternative drugs that would otherwise have been prescribed.

XII. INTRODUCTION TO RELATORS

A. Background of Relators

i. Jim Banigan

190. Jim Banigan is a seventeen-year veteran of Organon, where he worked until his termination on March 31, 2008. Banigan first came to Organon in 1991 as a sales representative. He was later promoted to become one of Organon's six original Regional Account Managers. He was then promoted to National Account Manager and began supervising and training other Regional Account Managers. After five years with Organon, Banigan became Manager of Government Accounts in 1996. In that position, he was responsible for Government Contracting and Government Contracts Administration, a position created for him and previously shared by several departments. Banigan became responsible for assuring that Organon drugs were on states' Medicaid formularies.

191. Banigan moved on to the Trade Department of Organon's National Accounts Division in early 2006, into an executive position in which he interacted with wholesalers, retail chains, and specialty pharmacies.

192. Although Banigan was not involved directly with the creation of the Medicaid scheme, he was a member of the leadership team within the same Managed Care department that developed the scheme and, as a result, had contemporaneous knowledge of it.

ii. Richard Templin

193. Richard Templin worked in management in the pharmaceutical arena for twelve years before joining Organon in March 2006. Templin, like Banigan, was an executive with Organon's Managed Markets Division. He was the Director of Government Accounts at the

time of his termination. He was hired by the Vice President of Managed Markets and reported to an Executive Leadership member until his termination on June 16, 2008.

194. When Templin first came to Organon, the Medicaid scheme was winding down; he nevertheless became aware of the scheme through the normal course of his job activities.

B. Relators' Discovery of Organon's Medicaid Scheme

195. Templin first became aware of the scheme to defraud Medicaid on Wednesday, September 27, 2006, while attending an Organon launch meeting at the Venetian Hotel in Las Vegas. Templin was having a conversation with John Maddox, an Executive Account Manager for Organon with responsibilities for both the Long Term Care and Managed Markets accounts. The topic of government compliance arose, and Maddox divulged the existence of a "non-compliant" program that provided him with a "get-out-of-jail-free card with Organon." Organon was undergoing significant management changes at that time and it was not uncommon for management and non-management staff to express concerns regarding their job security. Maddox did not offer any significant detail about the program. Templin did not pursue the topic further with Maddox that night, but decided to investigate further on his own.

196. Over the next few months, Templin was able to gather some information about the scheme Maddox had mentioned. He learned that the program centered on marketing the "opportunity to profit" in the long-term care market and was focused exclusively on the product Remeron.

197. Templin broached the subject with a number of colleagues in late 2006 or early 2007, including Butch McKenna, Manager for Senior Care, National Accounts Division, who had created and managed the long-term care sales force. That sales force, Templin learned from McKenna, was set up specifically and with the expressed and written goal to implement the

Medicaid scheme in the long-term care market. In addition, the long-term care sales force was responsible for working collaboratively with the Government Accounts department, led by Jim Banigan, to secure formulary access for Medicaid patients, many of whom were residing in their customers' nursing home facilities.

198. McKenna disclosed to Templin that the program to which Maddox had alluded, marketing the "opportunity to profit" on Remeron to pharmacy providers, was called "Time to Profit." In fact, McKenna possessed copies of a long-term care marketing binder that detailed the scheme. McKenna mentioned that Organon's compliance officer Rhetta Rierdan had contacted him earlier with a request to return to the home office all marketing materials that dealt with marketing the "opportunity to profit," and McKenna, wishing to keep the binder, had falsely responded that he no longer had it. McKenna believed that the officer sought to destroy any materials he gathered. McKenna echoed Maddox's belief that the program was illegal and that he considered his knowledge of the program to be his "golden ticket" to raise if anything were to go wrong for him at Organon. As a result, he planned to continue to hold onto all related materials at his home office.

199. Templin first spoke to Jim Banigan about the Medicaid scheme in early April of 2007, hoping that Banigan had heard of it. Banigan confirmed the existence of the scheme. Banigan related that, in November of 2003, just as the scheme was winding down, Banigan heard about it from both McKenna, Director of Long Term Care Sales, and Maddox, Executive National Account Manager Long Term Care. Both discussions were prompted by changes in management and general concern over the leadership stability at Organon. McKenna had informed Banigan that he had direct knowledge of the Medicaid scheme and comprehensive documentation of marketing materials and other communications used to communicate to

customers how to maximize their profits by influencing providers to prescribe Remeron. McKenna had explained that the Marketing Department conspired with McKenna's sales team to market Remeron almost purely based upon profit potential. McKenna had told Banigan that he planned to hold his knowledge of the scheme "close to his vest" for the time being, but that if Organon attempted to "squeeze him out," he would use this evidence as his "insurance policy."

200. In a separate conversation with Maddox a day after Banigan heard about this scheme from McKenna, Maddox, too, implicated the Marketing Department for producing materials used to highlight how to maximize profit. Maddox indicated that the Marketing Department had recently become aware that the risk associated with continuation of this marketing scheme was too high. Maddox, McKenna and the rest of the long-term care sales team erased any evidence within their computers of "opportunity to profit" presentations and profit calculators. While Organon does have a general file retention policy allowing accounts managers to routinely clean out their electronic files, Maddox did not indicate to Banigan whether these actions of file destruction were brought about under that policy or from recommendations by general counsel for Organon.

201. Banigan had never seen for himself the marketing materials described by McKenna and Maddox, but after speaking with Templin, he decided to look for copies of those materials. He eventually secured original copies of two binders from former Remeron Executive brand director, Steve Vorrius, who had kept the original materials in his home. One of the binders was entitled "Long Term Care Sale Training" and the other was entitled "Remeron SolTab Therapeutic Interchange Program." Both have been described at length in Section V of this Complaint. Banigan was not able to locate these binders internally at Organon. While Remeron-related marketing materials at Organon's offices are currently kept in a segregated

document review area at Organon's offices for litigation purposes, Banigan gathered from Steve Vorrius, Executive Brand Director, that these materials may have never been divulged in the course of litigation. After reading through the binders and learning how blatantly Organon had promoted the "opportunity to profit"–along with added incentives in the form of kickbacks– in exchange for LTCPPs' commitments to engage in "therapeutic interchange" and conversion programs in the long-term care segment of Remeron's business, Banigan and Templin located and reviewed the contracts for Remeron's significant long-term care customers and found that the contracts' terms evidenced the same types of incentives reflected in the promotional materials. Moreover, the addenda to the contracts and accompanying communications reflected that as pressures mounted within Organon to grow the Remeron Tablet/Remeron SolTab business and to thwart impending generic competition, off-invoice discounts migrated to rebates. That move toward rebates assisted long-term customers in masking their true acquisition costs. In particular, rebates were preferred among long-term care providers who operated businesses within states in which Medicaid agencies benchmarked reimbursement upon actual acquisition cost.

202. Further, Banigan and Templin realized that long-term care contracts had continuously been extended to guarantee maximum discounts. Those extensions would have required the cooperation of the sales, marketing, and account management groups. In addition, shared services such as legal, finance, and meeting planning would have had to be involved in order to secure approval and financial resources to support the scheme.

203. Banigan and Templin also located draft copies of both McKenna's and Maddox's 2001 business plans, which further evidence the promotion of the "opportunity to profit" and other financial incentives to pharmacy providers.

C. Retaliation of Relators Banigan and Templin

204. Organon and Schering took adverse employment actions against Banigan and Templin for investigating their drug-pricing practices. Both Banigan and Templin were terminated after questioning Organon's pricing practices.

i. Jim Banigan

205. As Manager of Government Accounts from 1996 until early 2006 (when Banigan was promoted to an executive position in the Trade Department of Organon's National Accounts Division), Banigan was responsible for government price calculations. During that time, Banigan performed government pricing calculations utilizing an Organon-developed system that was unreliable and would sometimes generate incorrect calculations. Banigan complained repeatedly to Organon's management about this problem from about 1996 until 1999. In response, Organon eventually hired a third-party auditor, Envision Consulting Group ("Envision"), to audit its system. Even then, due to Organon's lack of financial commitment to diagnosing the cause of the system's calculation errors, Envision was able to offer only a quick and limited audit, relying largely on issue-spotting assistance from Organon employees such as Banigan. Although Envision provided Organon with a report regarding its findings, Banigan was never allowed to see the report. Banigan nevertheless learned from the Envision auditor that the audit found defects in Organon's pricing calculation system, confirming that it was unreliable. Beginning in early 2006, positioning itself for sale, Organon finally decided to spend the required money to hire a team of experts to set up a new government pricing system that could withstand an audit and survive the due diligence process of a corporate sale. As a result, the Organon-developed government pricing system was corrected by the third quarter of 2006,

and a new system developed by outside experts was put into place in October 2007. Previous pricing errors were not corrected and were not reported to the federal or state Governments.

206. In the fall of 2007, following Schering Plough's decision to purchase Organon, Schering Plough began its due diligence review of Organon's government pricing area. Schering Plough hired the same auditor, Envision Consulting Group, to audit Organon's government pricing area. Strangely, throughout its due diligence work, Envision made only limited contact with Banigan, then Director of Trade, and Templin, then Director of Government Accounts. Moreover, Schering Plough carefully limited Envision's audit to the most recent quarter calculations, which had been performed using Organon's revamped government pricing system. Thus, the audit inevitably failed to reveal the government pricing discrepancies stemming from the old system. Envision was well aware of the pricing discrepancies caused by the old calculation system, of course, and likely informed Schering Plough of these defects. Schering Plough purposefully requested Envision's audit to be limited to only the most recent quarter calculations in order to avoid having formal notice of any older defects.

207. In November 2007, shortly after Envision performed the audit and declared that there were limited or insignificant problems with the most recent quarter calculations, Schering Plough bought all shares of Organon BioSciences, the holding company for Organon's pharmaceutical operations. As a result of the sale, Organon's employees were required to apply for positions in Schering Plough. Banigan applied for two jobs for which he was qualified based on his prior experience at Organon: 1) Director of Specialty Pharmacy Markets, and 2) National Account Manager, a non-supervisory sales job. Schering Plough offered Banigan the lesser of the two positions, even though Schering Plough's management admitted that Banigan was the only candidate who met the job qualification posted for the Director of Specialty Pharmacy

Markets position. On March 31, 2008, Schering Plough terminated Banigan, stating that there was no comparable position for him, even though he was qualified these open positions in the new company. Banigan was unable to accept the severance package that he was offered, because it encompassed a pledge affirming that he did not know of any fraud committed by the company.

ii. Richard Templin

208. Templin worked as the Director of Government Accounts at Organon from March 2006 until June 16, 2008. In fall 2007, Organon placed Templin on a team of individuals, referred to as the "clean team," reviewing the government pricing area as part of Schering Plough's due diligence review of Organon. The team included both an Organon section and a Schering Plough section, but each section communicated solely with and through the team leader, Envision, and not to each other.

209. Months into the due diligence period, Templin observed that Schering was neglecting to conduct any substantial due-diligence inquiry into government contracts. Templin took particular notice of Schering's election to hire Envision to audit only the most recent quarter. Concerned, Templin discussed his knowledge of the historical pricing practices—including Public Health Services contracts and recalculations of best price calculations based on problems with the Public Health Services contracts— with other Organon clean team members, including Jim Harmon, Vice President Managed Markets for Organon.

210. In February 2008, Templin notified Debbie Kane, Vice President of Finance for Schering Plough, of the need to report these practices in light of requirements in Schering Plough's Corporate Integrity Agreement. In response, Kane moved to have Templin terminated immediately and stated that "Senior Management would never approve of that."

211. Templin then reported the historical pricing discrepancies and practices to Schering Plough's Integrity Hotline on March 3, 2008. Within three weeks after Templin filed his complaint with Schering Plough's Integrity Hotline and had follow-up discussions with Schering Plough, Schering Plough placed Templin on administrative leave, which lasted from March 25, 2008 through his termination on June 16, 2008. During his period of placement on administrative leave, Schering Plough discouraged Templin from coming into the office. In addition, on May 30, 2008, Schering Plough terminated Templin's Blackberry access. Templin's access to the office became so limited by the time of his termination that Schering Plough's Human Resources department was forced to contact Templin through the website www.Linkedin.com to inform him of his exit interview.

212. During his exit interview, Templin learned from Human Resources representatives Beth Perrone and Dorine Hirtz-Ganz that Envision had told Organon that Templin had claimed that he was himself responsible for the historical pricing problems involving the Public Health Services contracts. Perrone and Hirtz-Ganz added that such actions were against Schering Plough's policies and constituted the grounds for his termination. Contrary to their assertions, of course, the pricing actions taken by Templin were in accordance with Organon's policies and procedures and with the approval of Organon's senior management and legal department of Organon. Apparently worried that Templin would file suit under the False Claims Act, Schering-Plough offered Templin a severance package contingent on his release of certain claims, including an express provision requiring Templin to release any and all claims that could be asserted under the False Claims Act or under any state *qui tam* statute. Templin refused to sign this agreement and thus received no severance payment.

XIII. ACTIONABLE CONDUCT BY ORGANON, PHARMERICA, AND OMNICARE UNDER THE FALSE CLAIMS ACT

A. Applicable Law

i. The False Claims Act

213. This is an action to recover damages and civil penalties on behalf of the United States and Relators Banigan and Templin arising from the false or fraudulent statements, claims, and acts by Organon, PharMerica, and Omnicare made in violation of the False Claims Act, 31 U.S.C. §§ 3729–3732.

214. For conduct occurring before May 20, 2009, the False Claims Act ("FCA") provides that any person who:

(a) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

215. For conduct occurring on or after May 20, 2009, the FCA provides that any person who:

(a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to get a false or fraudulent claim paid (except that this language applies to all claims pending on or after June 7, 2008)

(c) conspires to defraud the Government by committing a violation of the FCA;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government.

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

216. The FCA allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in Federal District Court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730.

217. Based on these provisions, Relators Banigan and Templin, on behalf of the United States Government and the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago (collectively the "states") seek through this action to recover damages and civil penalties arising from Organon's causation of the submission of false claims to the federal and state governments. In this case, such claims were submitted to the federal Government for payment for Remeron Tablet and Remeron SolTab. Relators believe that the United States and the states have suffered significant damages as a result of false claims for payment for Remeron Tablet and Remeron SolTab.

218. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the alternative, Relators are original sources as defined therein. Relators have direct and independent knowledge of the information on which the allegations are based, as required pursuant to 31 U.S.C. §§ 3730(b) and (e). Relators have voluntarily provided information, oral and/or written, and have sent disclosure statement(s) of all material evidence, information and documents related to this complaint, both before and after filing, to the Attorney General of the United States, the United States Attorneys for the Southern District of Texas and the District of Massachusetts, and the Attorneys General of the various states, commonwealths, and the District of Columbia.

ii. The Federal Anti-Kickback Statute

219. In pertinent part, the Anti-Kickback Statute provides:

> (b) Illegal remuneration
>
> 1. whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

> 2. whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> 3. Paragraphs (1) and (2) shall not apply to—
>
> (A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

42 U.S.C. § 1320a-7b(b). A violation of the Anti-Kickback Statute is "false" for purposes of the FCA. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, codified as 42 U.S.C. § 1320a-7b(g). Those who violate the statute also are subject to exclusion from participation in federal health care programs, and civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

220. The purpose of the Anti-Kickback Statute is to prohibit such activities in order to secure proper medical treatment and referrals and to limit unnecessary treatments, services, or

goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089 (proposed Jan. 23, 1989) (to be codified 42 C.F.R. pt. 1001).

B. Fraudulent Conduct by Organon, PharMerica, and Omnicare Violates the FCA

i. Organon Caused Long-Term Care Pharmacy Providers to Submit False Claims by Offering Kickbacks and Long-Term Care Pharmacy Providers Solicited and Accepted Kickbacks in Violation of the Anti-Kickback Statute and the FCA

221. The Anti-Kickback Statute prohibits the offer or acceptance of remuneration to induce a physician to prescribe a drug. Organon violated the Anti-Kickback Statute by offering significant discounts and rebates to its GPO and long-term care pharmacy provider customers in exchange for prescriptions for Remeron Tablet and Remeron SolTab. Organon's 1999 and 2000 contracts with GPOs such as GeriMed, Managed Healthcare Associates, Owen and Committed Provider Services, provided for significant discounts and rebates on Remeron Tablet applicable only to the long-term care pharmacy provider members of these GPOs. Organon's 1999 and 2000 contracts with the most prominent GPOs, such as GeriMed, Managed Healthcare Associates, Owen and Committed Provider Services, provided long-term care pharmacy provider members with **8% to 14.8% "ramp-up" charge-back discounts** for the first five months, followed by **8% to 15% chargeback discounts** after that, depending on the market share held by Remeron Tablet for that member of the GPO. These market-tier discounts were based on the performance of individual long-term care pharmacy providers, not the performance of the GPO as a whole. In exchange for these discounts, Organon required the long-term care pharmacy providers to promote Remeron Tablets to their individual pharmacies.

222. Beginning in late 2000 and early 2001, Organon began negotiating with long-term care pharmacy providers directly, offering new incentives in addition to the market share discounts already in place. Organon added ramp-up discounts, "conversion" rebates tied to conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions, and "therapeutic interchange" bonuses conditioned on LTCPPs bestowing Remeron Tablet and Remeron SolTab with a "preferred" status and engaging in an active therapeutic interchange program. In addition, Organon moved from offering discounts to offering off-invoice rebates, allowing long-term care pharmacy providers to hide their true costs. Two long-term pharmacy providers, PharMerica and Omnicare, eventually agreed to contract directly with Organon; the others remained members of GPOs while individually negotiating contract terms.

223. In addition, to expand and maintain its market share for its drugs Remeron Tablet and Remeron SolTab, Organon offered and long-term care pharmacy providers, such as PharMerica, Omnicare, NeighborCare, NCS Healthcare, APS, and Sunscript, solicited kickbacks to purchase and recommend Remeron Tablet and Remeron SolTab and engage in therapeutic interchange programs for Remeron products. These kickbacks included, but were not limited to, data sharing agreements, research and educational grants, support of annual meetings and continuing education programs, payment for advertising initiatives, offers of nominally-priced Remeron product, entertainment, gifts, and other inducements.

224. Organon's fraudulent schemes to induce customers to purchase its products and the solicitation and acceptance of kickbacks by PharMerica and Omnicare violated the Anti-Kickback Statute and the FCA, 31 U.S.C. § 3729 (a).

225. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the Government's payment decision.

226. Because of the illegal acts described above, Organon made millions of dollars in sales of Remeron Tablet and Remeron SolTab to Medicaid patients it would not otherwise have achieved. Additionally, because of the illegal acts described above, PharMerica and Omnicare made profits from the substitution of other drugs for Remeron Tablet and Remeron SolTab at Medicaid's expense. The ultimate submission by long-term care pharmacy providers of false claims to the state Medicaid programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Consequently, the states and the United States Government have suffered substantial damages.

ii. Organon Conspired with Its Long Term Care and GPO, Customers to Defraud Medicaid in Violation of the FCA

227. Organon and long-term care pharmacy providers, including PharMerica, Omnicare, and Sunscript, NCS Healthcare, NeighborCare, and American Pharmaceutical Services, as well as GPOs, entered into agreements and conspired with one another to submit false claims for reimbursement for Remeron Tablet and Remeron SolTab prescriptions to state Medicaid programs and to receive reimbursement for these drugs to which the customers were not entitled.

228. As part of the scheme and agreement to obtain reimbursement for Remeron Tablet and Remeron SolTab prescriptions in violation of the state Medicaid programs' reimbursement policies, Organon and its pharmacy customers conspired and agreed to perform acts to effectuate the conspiracy.

229. As described more fully above, Organon's 1999 and 2000 contracts with GPOs provided for significant discounts and rebates on Remeron Tablet applicable only to the long-term care pharmacy provider members of these GPOs in exchange for the promotion of Remeron Tablets to their individual pharmacies.

230. Beginning in late 2000 and early 2001, Organon began offering new incentives in addition to the market share discounts already in place. Organon added ramp-up discounts, "conversion" rebates tied to conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions, and "therapeutic interchange" bonuses conditioned on LTCPPs bestowing Remeron Tablet and Remeron SolTab with a "preferred" status and engaging in an active therapeutic interchange program. In addition, after complaints by long-term care pharmacy providers that these providers were passing through the discounts to the state Medicaid programs, Organon moved from offering discounts to rebates to allow long-term care pharmacy providers to hide their true costs.

231. Furthermore, Organon offered kickbacks in various forms to long-term care pharmacy providers in exchange for purchasing and recommending Remeron Tablet and Remeron SolTab and, in some cases, for engaging in therapeutic interchange programs for Remeron products. Organon's various kickback schemes included, but were not limited to, data sharing agreements, research and educational grants, support of annual meetings and continuing education programs, payment for advertising initiatives, offers of nominally-priced Remeron product, entertainment, gifts, and other inducements.

232. In furtherance of the conspiracy, Organon, PharMerica, and Omnicare entered into long-term care contracts providing for financial incentives in the form of ramp-up discounts and rebates that were routinely extended beyond the initial offering period, conversion rebates,

and therapeutic interchange bonuses. Organon's contracts with these providers and GPOs assured an increased amount of prescriptions for Remeron Tablet and Remeron SolTab and thereby a larger profit for all parties involved.

233. Moreover, Organon's long-term care pharmacy provider customers solicited kickbacks in the guise of corporate partnership programs from Organon to purchase Remeron Tablet and Remeron SolTab and convert prescriptions to Remeron.

234. In furtherance of the conspiracy, during the Remeron Medicaid scheme, compensation to PharMerica general managers and clinical directors was based in part upon the relative margin and opportunity to profit from Remeron Tablet and Remeron SolTab. In addition, PharMerica rewarded Organon Vendor of the Year in 2002 and Diamond Level for several years, for Organon's financial contributions to PharMerica's VIP program.

235. As they knew would be the case, Organon, PharMerica, and Omnicare's actions resulted in the submission to state Medicaid programs of false and fraudulent claims for reimbursement for Remeron Tablet and Remeron SolTab, violating the FCA, 31 U.S.C. § 3729 (a), and resulting in substantial damages to the United States.

iii. Organon Intentionally Decreased Its Rebate Liability to State Medicaid Programs

236. In submitting AMP and best price figures to CMS for Remeron Tablet and Remeron SolTab prescriptions, Organon knowingly or with reckless disregard for the truth made or used a false record or statement to conceal, avoid, or decrease its rebate payments to the state Medicaid programs owed under its rebate agreements.

237. Specifically, under the terms of the rebate agreements between Organon and the state Medicaid programs, Organon was required to pay rebates, the amount of which was

premised on calculations involving AMPs and best prices for Remeron Tablet and Remeron SolTab, which Organon reported quarterly to CMS.

238. Organon intentionally used massive and illegal discounts and rebates offered to GPOs and long-term care pharmacy providers to lower its AMP figures for Remeron Tablet and Remeron SolTab, resulting in a reduction of its rebate liability for Remeron Tablet and Remeron SolTab to the state Medicaid programs. In addition, Organon concealed its true "best price" from the Government by entering into separate agreements with long-term care pharmacy providers that essentially amounted to kickbacks. By failing to disclose these payments to Medicaid, Organon avoided reporting its true "best price" to Medicaid, thereby lowering its rebate liability to Medicaid.

239. Moreover, Organon avoided disclosing the true best price for Remeron Tablet and Remeron SolTab. For example, at different times, Organon offered to Omnicare and PharMerica substantial quantities of Remeron SolTab at nominal prices contingent upon Omnicare and PharMerica's purchase of similar quantities of Remeron SolTab at a contracted discounted rate. Organon intentionally excluded the nominal price transactions when it reported its best price, even though it was required under best price law to disclose these transactions because they hinged upon a further purchase by Omnicare and PharMerica.

240. In addition, Organon entered into an arrangement with Kaiser that effectively allowed Organon to prospectively buy down discounts on Remeron by urging Kaiser to permit a shift in discounts to another product in order to avoid reporting its true best price on Remeron. In 2001, Organon realized that the discounts on Remeron under its 1997 fixed-price contact with Kaiser were setting a best price. In order to avoid reporting this true best price, Organon entered into an arrangement with Kaiser to increase the price of Remeron under the contract in exchange

for providing the same amount of discounts on Zemuron, another Organon product with low Medicaid sales. In order to conceal the best price violation, Organon backdated the amendment and removed transactions for Remeron from its chargeback system. Organon continued to extend the discounts under this contract until at least 2004. Organon therefore failed to report its true best price.

241. Organon also failed to maintain its 340B program covered entities membership list. Organon then sold Remeron to non-covered entities at government pricing, which Organon failed to report as part of its best price reporting, knowing that the best price would be lower and result in larger rebate liability.

242. Moreover, because the federal government uses best price reporting to set prices for 340B entities and the Federal Supply Schedule, Organon's failure to report the true best price caused other federal purchasers, such as 340B entities, the Department of Defense, the Veterans' Administration, the Bureau of Prisons, and the Bureau of Indian Affairs, to pay higher prices for Remeron Tablet and Remeron SolTab,

243. Organon's intentional reduction of its reported AMPs for Remeron Tablet and Remeron SolTab and purposeful avoidance of reporting best prices violated the FCA, 31 U.S.C. § 3729 (a), and caused the federal and state governments to suffer substantial damages as a result.

iv. Organon's Off-Label Marketing Scheme Violated the FCA

244. Moreover, Organon violated the FDCA by distributing drugs, specifically Remeron Tablet and Remeron SolTab, that were misbranded. Organon's promotion of Remeron Tablet and Remeron and SolTab constituted illegal misbranding because the drugs' labeling was false or misleading, their labeling did not bear adequate directions for use, their labeling did not

bear adequate warnings against use in children and those with pathological conditions, and/or their labeling did not bear adequate warnings against unsafe dosage or methods of administration or application. Organon's conduct flies in the face of the guidances and regulations that pertain to off-label marketing.

245. In addition, upon information and belief, Organon purposefully manipulated drug compendia, such as DRUGDEX, through the use of false statements or records or material omissions and caused them in some cases to list desired off-label uses based on evidence that did not actually substantiate or fortify the uses with the intent of getting Medicaid to reimburse these off-label uses. Organon knew that its false marketing materials and false and misleading representations by its sales representatives would cause physicians to submit claims for fraudulent Medicaid reimbursement.

246. Organon's fraudulent scheme to aggressively and illegally market its drugs for off-label use and integrate illegal kickbacks into its off-label sales campaigns led to increased prescriptions for its drugs. Virtually all off-label prescriptions for these drugs for which Medicaid paid were a direct result of these illegal sales campaigns. Thus, these Medicaid claims for off-label prescriptions are tainted by the associated illegal kickbacks, as well as by Organon's "mislabeling" of its drugs. Organon's scheme violated the Anti-Kickback Statute and the FDA's prohibitions on the promotion of off-label uses, and therefore caused false claims to be submitted by long-term care pharmacy providers in violation of the FCA. By taking part in this fraudulent scheme, Organon repeatedly and with continued knowledge violated the False Claims Act, 31 U.S.C. § 3729 (a).

v. Organon and Schering Plough Retaliated Against Banigan and Templin in Violation of the FCA

247. During and after Schering Plough's purchase of Organon, Banigan and Templin consistently raised questions to colleagues and management regarding the reliability of Organon's government pricing computer systems and the likely fraud upon the Government resulting from that unreliability. In response, Schering Plough terminated Banigan and Templin in 2008. Banigan and Templin have thus suffered negative employment consequences and have suffered damages, now and in the future.

vi. Damages

248. Under the FCA and applicable law, Remeron Tablet and Remeron SolTab prescriptions resulting from Organon's fraudulent schemes should not have been submitted to state Medicaid programs. The ultimate submission by long-term care pharmacy providers and by retail, mail-order and managed care pharmacies pharmacists of false claims to the state Medicaid programs was a foreseeable factor in the Government's loss, and a consequence of the Defendants' fraudulent schemes.

249. In addition, Organon's actions caused Medicaid and other federal purchasers to pay an inflated price for Remeron Tablet and Remeron SolTab.

250. Furthermore, Organon's false reporting of its AMP and best price for Remeron Tablet and Remeron SolTab resulted in a reduced rebate paid to the state Medicaid programs.

251. Consequently, the states and the United States Government have suffered approximately $421.7 million in damages, which trebled is approximately $1.263 billion, stemming from improper Remeron Tablet and Remeron SolTab prescription costs.

XIV. CAUSES OF ACTION

A. COUNT I - FALSE CLAIMS (31 U.S.C. § 3729(a))

252. Relators reallege and hereby incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

253. Organon violated the Anti-Kickback Statute by offering significant discounts and rebates as well as other financial inducements to its GPO and long-term care pharmacy provider customers in exchange for prescriptions for Remeron Tablet and Remeron SolTab. As a result of those violations and Organon's off-label marketing scheme and conduct, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, and pharmacists to submit to the state Medicaid programs are false or fraudulent. Organon knowingly caused such false or fraudulent claims to be presented for payment or approval, in violation of 31 U.S.C. § 3729(a).

254. Additionally, Organon's long-term care pharmacy provider customers, such as Omnicare and PharMerica, violated the Anti-Kickback Statute by accepting Organon's kickbacks. Thus, all of the claims knowingly submitted by these long-term care pharmacy providers, such as the claims submitted by Omnicare and PharMerica, are false or fraudulent.

255. The United States Government paid the false and/or fraudulent claims.

256. By virtue of the false or fraudulent claims that Organon knowingly caused to be presented or that Omnicare and PharMerica submitted, the United States Government has suffered substantial monetary damages.

B. COUNT II – FALSE RECORDS OR STATEMENTS (31 U.S.C. § 3729(a))

257. Relators reallege and incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

258. Organon, Omnicare and PharMerica knowingly made or used, or caused to made or used, false records or statements, or omitted material facts (a) to get false or fraudulent claims paid or approved by the Government, or (b) that were material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a). The false records or statements included, but were not limited to, the false or misleading materials or other statements provided to GPOs, long-term care pharmacy providers, consultant pharmacists, and physicians to induce physicians to prescribe and/or switch and pharmacists to switch patients' prescriptions to Remeron and/or Remeron SolTab, and the physicians', pharmacists', and/or long-term care pharmacy providers' false certifications, express or implied, and representations of full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute. Compliance with federal and state laws and regulations were conditions of payment. Each prescription that was written as a result of the Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to Medicaid or other federal health insurance program represents a false and/or fraudulent claim for payment.

259. By virtue of the false record or statement that Organon, Omnicare, and PharMerica made or used, or caused to be made or used, the United States Government has suffered substantial monetary damages.

C. COUNT III – CONSPIRACY (31 U.S.C. § 3729(a))

260. Relators reallege and incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

261. Organon conspired with its GPO and long-term care pharmacy provider customers, such as Omnicare and PharMerica, by paying kickbacks, which these customers

accepted, in violation of the Anti-Kickback Statute, to induce these customers to purchase drugs from Organon, thereby causing all of the claims submitted by long-term care pharmacy providers, pharmacies, and pharmacists to Medicaid for those drugs to be false or fraudulent. Accordingly, Organon, Omnicare, and PharMerica conspired to defraud the United States by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a).

262. By virtue of the false and/or fraudulent claims that Organon, Omnicare and PharMerica conspired to get allowed or paid, the United States has suffered substantial monetary damages.

D. COUNT IV– REVERSE FALSE CLAIMS (31 U.S.C. § 3729(a))

263. Relators reallege and incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

264. Organon reduced its rebate liability to state Medicaid programs by: (1) including the illegal discounts and rebates offered to its GPO and long-term care pharmacy provider customers to lower its AMP figures for Remeron Tablet and Remeron SolTab, (2) concealing its true "best price" from the Government by entering into separate agreements with long-term care pharmacy providers that amounted to kickbacks, (3) avoiding disclosure of the true best price for Remeron and Remeron SolTab by mischaracterizing transactions as "nominal" and concealing "best price" violations, and (4) selling Remeron Tablet and Remeron SolTab at 340B prices to entities not qualified to receive this pricing, affecting Remeron's true commercial "best price." As a result of these schemes, Organon knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay money to the Government. The false records or statements included but were not limited to (1) Organon's false pricing reports to the Government; and (2) Organon's and the long-term care pharmacy

providers' false certifications and representations of full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the "Best Price" statute.

265. By virtue of the false records and/or statements that Organon made, used, or caused to be made or used, the United States has suffered substantial monetary damages.

E. COUNT V – RETALIATION (31 U.S.C. § 3730(H))

266. Relators reallege and incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

267. In violation of the False Claims Act § 3730(h), Organon and Schering Plough took negative employment actions against Relators in response to their investigation and initiation of this claim.

268. As a result of Organon and Schering Plough's conduct, the Relators suffered negative employment consequences and have suffered damages, now and in the future.

RELIEF

269. On behalf of the United States Government, Relators seek to receive monetary damages equal to three times that suffered by the United States Government. In addition, Relators seek to receive all civil penalties on behalf of the United States Government in accordance with the False Claims Act.

270. The *qui tam* Relators seek to receive on their own behalf all monetary damages to which they are entitled for Organon and Schering Plough's retaliatory conduct against them. In addition, the Relators seek punitive damages in their own behalf.

271. Relators seek to be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act.

272. Relators seek to be awarded all costs and expenses for this action, including attorneys' fees and court costs.

273. Relators seek to be awarded all other relief on behalf of Relators or the United States Government to which either may be entitled and that the Court deems just and proper.

PRAYER

WHEREFORE, Relators pray that this Court enter judgment on behalf of Relators and against Defendants for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the United States Government as a result of Defendants' conduct;

b. Civil penalties against Defendants up to $11,000 for each violation of 31 U.S.C. § 3729;

c. Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. ' 3730(d);

d. Relators be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court;

e. Relators' individual damages;

f. Pre-judgment interest at the highest rate allowed by law to the Relators for the retaliatory conduct by Organon and Schering Plough;

g. Punitive damages to the Relators for the retaliatory conduct by Organon and Schering Plough; and

h. All other relief on behalf of Relators or the United States Government to which either may be entitled and that the Court deems just and proper.

F. COUNT VI - CALIFORNIA FALSE CLAIMS ACT

274. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

275. This is a *qui tam* action brought by Relators and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq*.

276. Cal. Gov't Code § 12651(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the s*tate or* of any political division thereof, a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
>
> ***
>
> (7) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

277. Organon, Omnicare and PharMerica knowingly violated Cal. Gov't Code § 12651(a) from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the California Anti-Kickback Statutes (Cal. Bus. & Prof. Code §§ 650-650.1 and Cal. Welf. & Inst. Code §14107.2), as described herein.

278. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the California Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the California Anti-Kickback Statutes (Cal. Bus. & Prof. Code §§ 650-650.1 and Cal.

Welf. & Inst. Code §14107.2). Compliance with federal and state laws and regulations were conditions of payment.

279. The State of California, by and through the California Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

280. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of California's payment decision.

281. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of California's loss, and a consequence of the scheme.

282. As a result of the Defendants' violations of Cal. Gov't Code §12651(a), the State of California has been damaged.

283. There are no bars to recovery under Cal. Gov't Code §12652(d)(3), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of themselves and the State of California.

284. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF CALIFORNIA:

(1) Three times the amount of actual damages which the State of California has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of up to $11,000 for each false claim that Organon, Omnicare and PharMerica presented or caused to be presented to the State of California;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

G. COUNT VII - DELAWARE FALSE CLAIMS AND REPORTING ACT

285. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

286. This is a *qui tam* action brought by Relators and the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

287. 6 Del. C. § 1201(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
>
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.
>
> ***
>
> (7) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

288. Organon, Omnicare, and PharMerica knowingly violated 6 Del. C. § 1201(a) from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Delaware Anti-Kickback Statute (31 Del. C. § 1005), as described herein.

289. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Delaware Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and Delaware Anti-Kickback Statute (31 Del. C. § 1005). Compliance with federal and state laws and regulations were conditions of payment.

290. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

291. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Delaware's payment decision.

292. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Delaware's loss, and a consequence of the scheme.

293. As a result of the Defendants' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged.

294. There are no bars to recovery under 6 Del. C. § 1206(c), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 6 Del. C. § 1203(b) on behalf of themselves and the State of Delaware.

295. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare, and PharMerica:

To the STATE OF DELAWARE:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare, and PharMerica caused to be presented to the State of Delaware;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to 6 Del. C. § 1205, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

H. COUNT VIII - DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

296. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

297. This is a *qui tam* action brought by Relators and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

298. D.C. Code § 2-308.14(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

(3) conspires to defraud the District by getting a false claim allowed or paid by the District;

***

(7) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

299. Organon, Omnicare, and PharMerica knowingly violated D.C. Code § 2-308.14(a) from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the District of Columbia Anti-Kickback Statute (D.C. Code § 4-802), as described herein.

300. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the District of Columbia Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the District of Columbia Anti-Kickback Statute (D.C. Code § 4-802). Compliance with federal and state laws and regulations were conditions of payment.

301. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

302. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the District of Columbia's payment decision.

303. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the District of Columbia's loss, and a consequence of the scheme.

304. As a result of the Defendants' violations of D.C. Code § 2-308.14(a) the District of Columbia has been damaged.

305. There are no bars to recovery under D.C. Code §2-308.15(c)(2), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this

action pursuant to D.C. Code § 2-308.15(b) on behalf of themselves and the District of Columbia.

306. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon. Omnicare and PharMerica:

To the DISTRICT OF COLUMBIA:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare, and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the District of Columbia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

I. COUNT IX - FLORIDA FALSE CLAIMS ACT

307. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

308. This is a *qui tam* action brought by Relators and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

309. Fla. Stat. § 68.082(2) provides liability for any person who-

1. knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

3. conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;

4. knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

310. Organon, Omnicare and PharMerica knowingly violated Fla. Stat. § 68.082(2) from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Florida Anti-Kickback Statute (Fla. Stat. § 409.920), as described herein.

311. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Florida Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Florida Anti-Kickback Statute (Fla. Stat. § 409.920). Compliance with federal and state laws and regulations were conditions of payment.

312. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, paid the false and/or fraudulent claims.

313. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Florida's payment decision.

314. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Florida's loss, and a consequence of the scheme.

315. As a result of the Defendant's violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged.

316. There are no bars to recovery under Fla. Stat. § 68.087(3), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of themselves and the State of Florida.

317. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF FLORIDA:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Florida;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

J. COUNT X – GEORGIA FALSE CLAIMS ACT

318. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

319. This is a *qui tam* action brought by Relators and the State of Georgia to recover treble damages and civil penalties under the Georgia False Claims Act, Georgia Code Ann. § 49-4-168 *et seq*.

320. Georgia Code Ann. § 49-4-168.1 provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

321. Organon, Omnicare and PharMerica knowingly violated Georgia Code Ann. § 49-4-168.1 from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute, as described herein.

322. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Georgia Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute. Compliance with federal and state laws and regulations were conditions of payment.

323. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

324. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Georgia's payment decision.

325. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Georgia's loss, and a consequence of the scheme.

326. As a result of the Defendants' violations of Georgia Code Ann. § 49-4-168.1, the State of Georgia has been damaged.

327. There are no bars to recovery under Georgia Code Ann. § 49-4-168.2, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Georgia Code Ann. § 49-4-168.1 on behalf of themselves and the State of Georgia.

328. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF GEORGIA:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Georgia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Georgia Code Ann. § 49-4-168.2 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

K. COUNT XI - HAWAII FALSE CLAIMS ACT

329. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

330. This is a *qui tam* action brought by Relators and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq*.

331. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

332. Organon, Omnicare and PharMerica knowingly violated Haw. Rev. Stat. §661-21(a) from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Hawaii Anti-Kickback Statute (Haw. Rev. Stat. § 346-43.5), as described herein.

333. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Hawaii Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback

Statute and the Hawaii Anti-Kickback Statute (Haw. Rev. Stat. § 346-43.5). Compliance with federal and state laws and regulations were conditions of payment.

334. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

335. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Hawaii's payment decision.

336. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Hawaii's loss, and a consequence of the scheme.

337. As a result of the Defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged.

338. There are no bars to recovery under Haw. Rev. Stat. § 661-28, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of themselves and the State of Hawaii.

339. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF HAWAII:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Hawaii;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

L. COUNT XII - ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

340. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

341. This is a *qui tam* action brought by Relators and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq*.

342. 740 ILCS 175/3(a) provides liability for any person who-

1. knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

3. conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

4. knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

343. Organon, Omnicare and PharMerica knowingly violated 740 ILCS 175/3(a) from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Illinois Anti-Kickback Statute (305 ILCS 5/8A-3(b)), as described herein.

344. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Illinois Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Illinois Anti-Kickback Statute (305 ILCS 5/8A-3(b)). Compliance with federal and state laws and regulations were conditions of payment.

345. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

346. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Illinois's payment decision.

347. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state

Medicaid programs was a foreseeable factor in the State of Illinois's loss, and a consequence of the scheme.

348. As a result of the Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged.

349. There are no bars to recovery under 740 ILCS 175/4(e)(4), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 740 ILCS 175/3(b) on behalf of themselves and the State of Illinois.

350. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF ILLINOIS:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Illinois;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

M. COUNT XIII – INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

351. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

352. This is a *qui tam* action brought by Relators and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code §5-11-5.5-1 *et seq*.

353. Ind. Code §5-11-5.5-1(b) provides liability for any person who-

1. presents a false claim to the state for payment or approval;

2. makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

***

6. makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state ;

7. conspires with another person to perform an act described in subdivisions (1) through (6).

354. Organon, Omnicare and PharMerica knowingly violated Ind. Code §5-11-5.5-1(b) from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Indiana Anti-Kickback Statute (Ind. Code § 12-15-24-2), as described herein.

355. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Indiana Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term

care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Indiana Anti-Kickback Statute (Ind. Code § 12-15-24-2). Compliance with federal and state laws and regulations were conditions of payment.

356. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

357. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Indiana's payment decision.

358. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Indiana's loss, and a consequence of the scheme.

359. As a result of the Defendants' violations of Ind. Code § 5-11-5.5-1(b), the State of Indiana has been damaged.

360. There are no bars to recovery under Ind. Code § 5-11-5.5-7(f), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Ind. Code §5-11-5.5-1(b) on behalf of themselves and the State of Indiana.

361. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF INDIANA:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Indiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Ind. Code §5-11-5.5-6(a) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

N. COUNT XIV - LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

362. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

363. This is a *qui tam* action brought by Relators and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann.§ 46:437.1 *et seq.*

364. La. Rev. Stat. Ann. § 46:438.3 provides -

(a) No person shall knowingly present or cause to be presented a false or fraudulent claim;

(b) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds; and

(c) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

365. Organon, Omnicare and PharMerica knowingly violated La. Rev. Stat. Ann. § 46:438.3 from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Louisiana Anti-Kickback Statute (La. Rev. Stat. Ann. § 46:438.2(A)), as described herein.

366. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Louisiana Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Louisiana Anti-Kickback Statute (La. Rev. Stat. Ann. § 46:438.2(A)). Compliance with federal and state laws and regulations were conditions of payment.

367. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

368. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Louisiana's payment decision.

369. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state

Medicaid programs was a foreseeable factor in the State of Louisiana's loss, and a consequence of the scheme.

370. As a result of the Defendants' violations of La. Rev. Stat. Ann. § 46:438.3 the State of Louisiana has been damaged.

371. There are no bars to recovery under La. Rev. Stat. Ann. § 46:439.1(E), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to La. Rev. Stat. Ann. § 46:439.1(A) on behalf of themselves and the State of Louisiana.

372. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF LOUISIANA:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Louisiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 46:439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

O. COUNT XV - MASSACHUSETTS FALSE CLAIMS ACT

373. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

374. This is a *qui tam* action brought by Relators and the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. 12 § 5(A) *et seq.*

375. Mass. Gen. Laws Ann. 12 § 5B provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(4) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth or political subdivision thereof.

376. Organon, Omnicare and PharMerica knowingly violated Mass. Gen. Laws Ann. 12 § 5B from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Massachusetts Anti-Kickback Statute (Mass. Gen. Laws Ann. 118E §41), as described herein.

377. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and

PharMerica, pharmacists, and physicians to knowingly submit to the Massachusetts Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Massachusetts Anti-Kickback Statute (Mass. Gen. Laws Ann. 118E §41). Compliance with federal and state laws and regulations were conditions of payment.

378. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

379. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the Commonwealth of Massachusetts's payment decision.

380. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the Commonwealth of Massachusetts's loss, and a consequence of the scheme.

381. As a result of the Defendants' violations of Mass. Gen. Laws Ann. 12 § 5B, the Commonwealth of Massachusetts has been damaged.

382. There are no bars to recovery under Mass. Gen. Laws Ann. 12 § 5G, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mass. Gen. Laws Ann. 12 § 5C(2) on behalf of themselves and the Commonwealth of Massachusetts.

383. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the COMMONWEALTH OF MASSACHUSETTS:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the Commonwealth of Massachusetts;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann.12, §5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

P. COUNT XVI - MICHIGAN CLAIMS ACT

384. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

385. This is a *qui tam* action brought by Relators and the State of Michigan for treble damages and penalties under Michigan False Claims Act, Mich. Comp. L. § 400.601 *et seq.*

386. Mich. Comp. L. §§ 400.603, 400.606 and 400.607 provides liability for any person who-

(1) knowingly makes or causes to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit;

(2) knowingly makes or presents or causes to be made or presented to an employee or officer of this state claim under Medicaid;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim.

387. Organon, Omnicare and PharMerica knowingly violated Mich. Comp. L. §§ 400.603, 400.606 and 400.607 from at least 1999 to 2005 by violating the Federal Anti-Kickback Statute and the Michigan Anti-Kickback Statute (Mich. Comp. Laws § 400.604), as described herein.

388. As a result of Organon's off-label marketing, kickback and best price schemes, all of the claims that Organon caused long-term care pharmacies, such as Omnicare and PharMerica, pharmacists, and physicians to knowingly submit to the Michigan Medicaid program are false or fraudulent. Further, Organon caused physicians', pharmacists', and/or long-term care pharmacy providers, such as Omnicare and PharMerica, to falsely certify, expressly or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Michigan Anti-Kickback Statute (Mich. Comp. Laws § 400.604). Compliance with federal and state laws and regulations were conditions of payment.

389. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, paid the false and/or fraudulent claims.